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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,185	08/10/2000	John F. Gerber	GER-100XC1	6539

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/02/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/636,185

Applicant(s)
Gerber et al.

Examiner
Patricia Patten

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1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 31, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 5, 9-11, and 28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 9-11, and 28 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO 413) Paper No(s). |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 1, 4-5, 7, 9-11 and 28 are pending in the application and were presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is dependant upon a claim which has been canceled. Accordingly, claim 7 has not been further treated on the merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants contend that the microorganism which hybridizes to SEQ ID. NO 1. is specifically *Enterobacter cloacae* or *Pantoea* spp. However, there is no clear indication present within the Instant specification that the microorganisms present with the *Pasteuria* were actually *Enterobacter cloacae* or *Pantoea* spp.. Applicants have asserted that because the DNA of each of these microorganisms hybridizes with SEQ. ID. No. 1, that the microorganisms must be one of *Enterobacter cloacae* or *Pantoea* spp. However, the DNA sequences of bacteria are conserved, and it is found that many bacteria, especially *E.coli*, possess very similar DNA sequences to SEQ. ID. No. 1. For example, Goldstein (WO9905325 A-1) disclosed an *E.coli* which possessed 96% similarity to SEQ ID No. 1 (Fig 7). Thus, DNA comparison is not necessarily a nexus between microorganism distinction. Typically, the characteristics of microorganisms are extensively studied to ensure the correct identification of microorganism species; i.e.; antibacterial tolerance/resistance, starch hydrolysis, nitrate reduction and phenotype are just a few examples (please see Brock et al., 1991 pp. 474-482). Thus, DNA is but one small marker in actually identifying a species of microorganism. Although the DNA is similar (i.e., between

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E. cloacea and *E. coli*) the biochemistry of each respective bacteria is highly diverse and functionally distinct.

Therefore, lacking critical diagnostic identification with regard to the microorganism which hybridizes to SEQ ID NO. 1, it appears questionable whether the microorganisms were actually *Enterobacter cloacae* or *Pantoea* spp.

Claims 1, 4, 7 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing *Pasteuria* endospores with a microorganism which is identified by ATCC PTA-2324 (the deposited species), does not reasonably provide enablement for the growth of *Pasteuria* via administration of any microorganism which hybridizes to SEQ ID No. 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of

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experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

The art of microbiology is extensively diverse and highly unpredictable. The slightest change in DNA sequence can potentially bring about a functionally diverse species of microorganism. In the Instant case, as stated *supra*, it appears that many microorganisms could potentially hybridize to SEQ ID No. 1 such as *E.coli*. The Instant specification has not indicated an exact mode by which these microorganisms actually 'help' the *Pasteuria* to grow. This 'helper factor' which is disclosed in the Instant specification has also not been completely identified. It is not known what other microorganisms, besides the one deposited (ATCC PTA-2324) would actually produce this factor which appears to be the substantial crux for *Pasteuria* growth. The Instant specification contains no comparison of microorganisms which have actually helped *Pasteuria* production besides the deposited species. For example, Applicants postulate that the microorganism may be *E. Cloacae* or *Pantoea spp.*, however, have not performed any assays

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which would actually conclude that either of these organisms would actually facilitate the growth of *Pasteuria*, nor have they provided data with regard to other bacteria such as *E.coli* (which would hybridize to SEQ ID No. 1) which would facilitate *Pasteuria* growth.

The skilled artisan would need to perform undue experimentation to ascertain whether other bacteria, besides the deposited species would actually work commensurate in scope with the claimed invention. Because of the unpredictability of microorganisms, coupled with the fact that the DNA sequences appear to be conserved, the skilled artisan would perform this experimentation without expectation of success.

Limitation of the microorganism of Claim 1 to the deposited species will overcome this rejection.

Allowable Subject Matter

Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER R. TATE
PRIMARY EXAMINER